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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,776	01/10/2002	Michael C. Pfeil	DP-307032	3047

7590

08/06/2003

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EXAMINER

DRODGE, JOSEPH W

ART UNIT	PAPER NUMBER
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1723

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DATE MAILED: 08/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/045,776

Applicant(s)

PFEIL ET AL.

Examiner

Joseph W. Drodge

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: .

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6, 9-13, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fond patent 5,111,683 in view of Cosentino et al patent 4,021,341. Fond discloses a system for controlling flow in a dialysate circuit that includes a first flow path from dialysis fluid source to the dialysate side of a kidney dialysis machine [as in claims 10 and 19], the latter being a second source for a second flow path away from the machine; see figure 1 and column 1, lines 64-67. Also disclosed are first and second flow meter transducers that monitor flow rate properties [as in claims 1-3, 6, 9, 11-13, 16 and 17] that are initially uncalibrated. Fond also discloses starting flow through a bypass interconnection path and stopping flow to and from the second fluid source by control of respective pumps and valves upon which the flow through the flow paths is matched and the transducers are calibrated (column 4, lines 14-38) and finally, disconnecting of the interconnection to restart the flow from the second fluid source and

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later obtaining readings from the flow meter transducers during dialysis session operation (column 7, lines 59-61).

The claims differ in requiring that flow rates in the flow paths be controlled so as to match each other, utilizing data obtained from both the transducer readings during connection of the bypass path and transducer readings following reconnection of the second fluid source. However, Cosentino et al teach such flow matching (column 1, line 20-column 2, line 7, column 4, lines 49-51 and column 5, lines 12-25). It would have been obvious to one of ordinary skill in the art to have modified the Fond method and apparatus by providing means for such control of flow matching, as suggested by Cosentino et al, to stabilize the ultrafiltration or dialysis rate of the blood being purified.

Claims 4, 5, 7, 8, 14, 15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fond in view of Cosentino et al as applied to claims 1, 6, 11 and 16 above, and further in view of Lichtenstein patent 4,370,983. Fond further discloses positive displacement pumps 12 and 13.

These claims further differ in requiring the transducers to measure the flow rate by sensing differential pressure. Lichtenstein teaches controlled flow through the inlet and outlet lines of a dialysate flow circuit controlled by monitoring of flow rates (column 13, line 38 – column 14, line 17) with such differential pressure sensing (column 10, lines 50-61). It would have been further obvious to one of ordinary skill in the art to have provided flow meter transducers of the type which sense differential pressure, as taught by Lichtenstein, so as to provide increased accuracy of the monitoring of flow rate properties, by accounting for flow resistances.

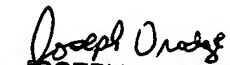
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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Polaschegg patent 6,280,632 and Kolberg patent 4,132,644 are of interest with respect to systems for controlling flow rates to and from kidney dialysis machines in both dialysis and blood flow circuits and bypass interconnections for such systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph W. Drodge at telephone number (703) 308-0403 between the hours of 8:30 and 5:00 on Monday through Friday.

JWD

August 4, 2003

  
**JOSEPH DRODGE**  
**PRIMARY EXAMINER**